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1-0909b

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

William A. Cook et al.

Patent No. 4,543,954

Issued October 1, 1985

EXERCISE RESPONSIVE CARDIAC PACEMAKER

August 9, 1988

LETTER IN RE. PATENT TERM EXTENSION APPLICATION FILED UNDER 35 U.S.C. § 156

Hon. Commissioner of Patents and Trademarks

Box Patent Ext.

Washington, D.C. 20231

Sir:

We are in receipt of certain correspondence of Charles E. Van Horn, Deputy Solicitor, Patent and Trademark Office, regarding the above-referenced matter, requesting supplementary information regarding events occurring between the effective date of the investigational device exemption, and the PMA submission and the approval dates all relating to the applicable regulatory review period. In compliance with Mr. Van Horn's request, which was received by the undersigned on or about July 28, 1988, the following information is respectfully submitted.

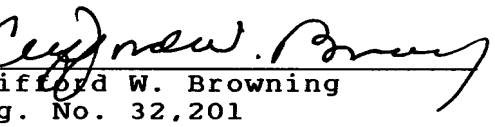
The investigational device exemption was approved on June 5, 1986, and the first clinical implants began in July of 1986. The first phase of the program was limited to ten (10) investigators and thirty-five (35) implants. After the subject products were implanted one month, an exercise treadmill test

was conducted. The data was summarized and presented to the Food and Drug Administration (FDA) on December 12, 1986. FDA released the second phase, which increased the number of clinical investigators to twenty-five (25) and the number of implant units to one hundred (100), on January 9, 1987. During the second phase, one month follow-up was required and, again, that data was summarized and the PMA was submitted on September 4, 1987.

Periodically, the number of investigators and the number of implants were increased to fifty (50) investigators and three hundred (300) implants. During the first quarter of 1988, a follow-up report was supplied to the FDA. FDA approval was granted on April 29, 1988. Only after April 29, 1988, were the subject products commercially approved to be freely distributed.

Purdue Research Foundation trusts the foregoing supplementary information will satisfy Mr. Horn's request for supplementary information.

Respectfully submitted,
PURDUE RESEARCH FOUNDATION

By 

Clifford W. Browning
Reg. No. 32,201
Woodard, Emhardt, Naughton
Moriarty & McNett
One Indiana Square, Suite 2000
Indianapolis, Indiana 46204

(317) 634-3456

Its Attorneys-Agents

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